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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

January 29, 1998

WARNING LETTER
SJN-98-06

Certified Mail
Return Receipt Requested

Mr. Ronald A. Elenbaas
President
Stryker Puerto Rico, Inc.
Stryker Corp. Surgical Division
4100 East Milham
Kalamazoo, MI 49002

Dear Mr. Elenbaas:

During an inspection of your medical device facility, Stryker Puerto Rico, Inc. Road #3, Km. 130.2, Arroyo, Puerto Rico conducted during October 23 to December 16, 1997, our investigator documented deviations from Title 21, Code of Federal Regulations, Part 820, Quality Systems Regulations (previously titled Good Manufacturing Practices for Medical Devices). These deviations are in connection to your firms manufacturing of [redacted], and similar pulsed irrigator/suction system, which are medical devices as defined by Section 201 (h), of the Federal Food, Drug & Cosmetic Act (FD&C Act) causing these devices to be adulterated within the meaning of Section 501 (h) of the FD&C Act as follows:

1. Failure to establish and maintain adequate procedures as part of your quality system for acceptance activities as required by 21 CFR 820.80, in that your established receiving inspections do not detect all nonconforming components, your combined acceptance activities do not address all instances of nonconforming product, and your acceptance records are incomplete. We refer you to FDA483 Observation 1 for examples.

2. Failure to establish and maintain adequate procedures for control of nonconforming product, to conduct investigations and implement corrective and preventive actions in accordance with 21 CFR 820.90 and 820.100(a), including identifying existing and potential non-conformities, fully investigating the cause of nonconforming product, and employing appropriate statistical methods to detect recurring quality problems. We refer you to FDA483 Observation 2 for examples.

3. Failure to establish and document appropriate purchasing controls to evaluate component supplier's ability to meet specified quality requirements as required by 21 CFR 820.50(a)(1), and not employing and maintaining valid statistical techniques for sampling plans in accordance with 21 CFR 820.250.

Historical data and process capability studies dating back to February 1994 for several injection-molded components show continued supplier problems in meeting specifications, and items 1 & 2 above indicate that you have failed to adequately evaluate the capabilities of your supplier. In consonance, your sample plan and acceptance criteria may be inconsistent and raises concerns on the degree of discrimination of the sampling method, and moreover, the extent of the sample size. Also, the same general sampling plan and technique are used regardless of the history of suppliers, component changes and failure rate data. Reference to FDA483 Observation 4.

4. Failure to maintain and follow change control procedures, evaluate validation or verification needs, review, document, and formally approve changes in accordance with 21 CFR 820.30(i), [previously 820.100(a)(2)], in reference to FDA483 Observation 5. For example; the September 1994 "pinion gear" material change from [redacted] was not processed through your change control procedure and was not properly documented, and the lower limit of the outside diameter (O.D.) of the "pinion gear" was changed on 1/31/96 based on an obsolete specification drawing without considering an Engineering Cange Order (ECO) that was misfiled, never code numbered, and although implemented, not used in evaluating the impact of further reducing the specification on "gear tooth rollover".

5. Process validation activities fail to provide a high degree of assurance the process is in control ensuring predetermined specifications are consistently met as required in 21 CFR 820.75(a)&(c), in reference to FDA483 Observation 6. For example; the initial process validation done in April 1993 did not include crucial information, and the September 1994 validation qualify the new multi-cavity tools did not assess all components that changed to [redacted].

We acknowledge receipt of your letter dated January 8, 1998 which exclusively responds to FDA483 Observation #3 pertaining to the investigation of the 1997 sterility test quarterly dose audit failures for the [redacted] medical device. We still have some concerns about the lack of data to substantiate your investigation conclusions. Before responding and expanding on these concerns, we are seeking additional technical and scientific review. We also acknowledge receipt of your January 22, 1998 letter which responds to the remaining FDA483 Observations. Our review indicates your responses were not fully adequate for FDA483 Observations 1, 2, 4, 5 & 6 as mentioned above. The response to the FDA483 Observation 7 appear, if fully implemented, to adequately address the concerns of the investigator.

Note that the 1978 Good Manufacturing Pratices (GMP) for Medical Devices regulation was superseded on June 1, 1997 by the Quality System Regulation. Since the inspection involved the review of records and documented deficiencies prior to and after June 1, 1997, the above-stated deviations are cross referenced to the 1978 GMP.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to comply with the FD & C Act and to assure adherence to each requirement of the Quality System Regulations. Federal Agencies are advised of all issuance of warning letters about medical devices so that they can take this information into account when considering the award of contracts.

You should take prompt actions to correct these deviations. Failure to do so may result in regulatory action without further notice. These regulatory actions may include seizure and/or injunction.

Please notify the San Juan District Office in writing within fifteen (15) days of receipt of this letter, of the steps you have taken to correct the above noted violations, including the steps you are taking to prevent the recurrence of these or similar violations.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223. Attention Andres Toro, Compliance Officer.

Sincerely yours,

Samuel Jones
District Director

cc:

Mr. Wilfredo Ruiz
Acting General Manager
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